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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/972,035	10/04/2001	Daniel Albert Wettstein	1907.03	2866

26698 7590 11/30/2005

MYRIAD GENETICS INC.
INTELLECUTAL PROPERTY DEPARTMENT
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EXAMINER

HILL, MYRON G

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/972,035

Applicant(s)

WETTSTEIN ET AL.

Examiner

Myron G. Hill

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 26, 44-50, and 61-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23, 26, 44-50 and 61-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>5/2/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to amendment filed 8/24/05 and supplemental amendment filed 9/8/05.

This action is on claims 1-23, 26, 44-50, and 61-68.

Information Disclosure Statement

A signed and initialed copy of the IDS paper filed 5/20/05 is enclosed.

Rejections Withdrawn

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1- 23 and 44- 50 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The metes and bounds of the terms "homologue", and "fragment" are not clear.

Applicant has amended the claims and the rejection is withdrawn.

Rejections Necessitated by Amendment

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Claims 1-23, 26, 44-50, and 61-68 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant argues case law and cites prior art of the proteins involved in the complex, in the 8/24/05 response and case law of Capon in the supplemental response.

Applicant's arguments have been fully considered and not found persuasive.

The claims are drawn to two proteins that form a complex. The claims are not limited to the specific proteins or the binding regions that are known to interact. Some of the subsequent claims limit one of the protein members to a specific but the other is still variable. See claim 1 parts (c) and (iii), for example. The claims have been amended to 75% identity.

The claims do not require that the binding domains be present or intact, see claim 1 parts (c) and (iii), for example.

The written description is shown by disclosing enough examples commensurate with the claims. Applicant points to examples and Figures but these do not show the range of mutations allowed by the claims as written.

The rejection is maintained.

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Claims 1-23, 26, 44-50, and 61-68 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for GAGp6 (449-500) and TSG101 (7-390), does not reasonably provide enablement for all other fragments, homologues, portions with less than 100% identity, and other GAGs or TSGs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant appears to only argue the Enablement rejection in the response of 8/24/05.

Applicant argues that the specification teaches how to make protein complexes and it well known the art. Also, that the examiner puts the cart before the horse in that the specification does not teach specific assays to use the complex. Also, that the specification teaches that the first 14 aa of GAGp6 with the PTAP sequence and the n-terminal sequence of Tsg101 which include the EUV domain and that one of skill in the art can easily determine fragments and mutation and determine if the binding occurs.

Applicant's arguments have been fully considered and not found persuasive.

The grounds for enablement clearly include the requirement to make and use the product. The rejection is not based on how to make proteins but on what proteins/polypeptides are able to bind to form a complex as required by the claims.

The examples pointed to by applicant are focused on the specific binding domains. The claims are not limited to those regions. Only a sample of selected

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mutations are shown as discussed in the prior action and this is not commensurate in scope with the claims.

The rejection is maintained.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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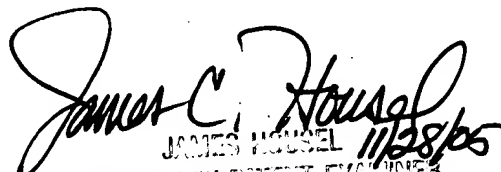
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 8:30 am-5 pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Myron G. Hill
Patent Examiner
28 November 2005



JAMES HOUSEL 11/28/05
SUPERVISORY PATENT EXAMINER
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